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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	**PAPER NUMBER**
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,671	IVARIE ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,21,28-35,37,41,46,52-56 and 59-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-21, 28-35, 37, 41, 46, 52-56, 59-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 02/21/07 has been acknowledged and fully considered.

Claims 20-21, 28-35, 37, 41, 46, 52-56, 59-61 are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is ***571-273-8300.***

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/21/07 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims *20-21, 28-35, 37, 41, 46, 52-56, 59-61 are* rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of transgenic avian, which lay eggs containing an exogenous protein of interest encompasses any transgenic avian (across class avis) which lays eggs containing any exogenous protein of interest

Applicant is referred to the guidelines for ***Written Description Requirement*** published January 5, 2001 in the Federal Register, Vol.66, No.4, pp.1099-1110. In analyzing whether the written description requirement is met for the claimed invention, it is first determined whether a claimed genus have been described through sufficient description of a representative number of species by their complete structure and function. Although, it is not realistic to expect that the "complete structure" of an animal, or even a cell, could be described, the phenotype a transgenic animal with desired traits remains unpredictable phenomenon because it is the result of a complex interaction between animal genetics and environment. Therefore, the inquiry required by this portion of the written description guidelines is interpreted to be whether the phenotypic consequences of altering the genotype have been described.

In this case, the few disclosed embodiments are not representative of the products claimed. At best the specification as filed discloses the making of chimeric chickens by transducing stage X embryos with NLB-CMV-BL (ALV-based vector) transduction particles (spec page 32, example-3, page 33 lines 3-9). Even though the specification as filed teaches the production of b-lactamase in egg white the specification fails to disclose any germ line transgenic avian (even a chicken) whose egg contains any exogenous protein produced (to be purified) by any transgene (which is not limited to a particular structure) present in the germ line of the transgenic avian and wherein the exogenous protein is produced in the transgenic oviduct.

Therefore, the limited disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that the applicants were in possessions of the huge genera recited in the claims at the time the application was filed. Furthermore, It is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable

(*See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966), Stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."*) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Thus it is concluded that the written description requirement is not satisfied for the claimed genera.

Claims 20-21, 28-35, 37, 41, 46, 52-56, 59-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the specification fails to disclose the making of any germ line transgenic avian (even a chicken) whose egg contains any exogenous protein produced (to be purified) by transgene present in the germ line of the transgenic avian and wherein the exogenous protein is produced in the transgenic oviduct, it is unclear how one skilled in the art use the invention as claimed (supra). The applicant's disclosure does not enable one skilled in the art to practice the invention as claimed without further undue amount of experimentation, which requires making any avian species which is germ line transgenic avian whose egg contains any exogenous protein produced by any transgene present in the germ line of the transgenic avian and wherein the exogenous protein is produced in the transgenic oviduct. At issue, under the enablement requirement of 35 U.S.C. 1 12, first paragraph is whether, given the Wands-factors, the experimentation was undue or unreasonable under the circumstances. "Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See Fields v. Conover, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970).

In instant case making a germ line transgenic avian capable of producing eggs that contains an exogenous protein of interest by using any transgene construct (which is not oviduct tissue specific) is not considered routine in the art and without sufficient guidance to a germ line specific transgenic avian species, transgene construct and the production of the encoded product in the egg white the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). The state of the art at the time of filing regarding making germ-line transgenic birds that produces an exogenous protein of interest in the eggs is considered highly unpredictable especially in view of low transgene transmission to the progeny. In addition viral the integration of viral vectors in the genome is random which further renders the any tissue specific (i.e. oviduct) highly unpredictable even in the presence of tissue specific promoter (Sang Mechanisms of Development 121:1179-1186, 2004, see pages 1182-1184; Mozdziak et al, Developmental Dynamics 229:414-421, 2004, see pages 416-418). Therefore considering the state of the art and limited amount of guidance provided in the instant specification, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the

reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-21, 28-35, 37, 41, 46, 52-56, 59-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 11/337,302. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope the germ-line transgenic avian which lays an egg contain an exogenous protein encoded by a transgene present in the germ-line of the transgenic avian, wherein the exogenous protein is produced in the transgenic oviduct as claimed in the instant application '671 is encompassed by an avian which lays an egg containing a protein wherein the protein is exogenous to the egg.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21, 28-35, 37, 41, 46, 52-56, 59-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 1-25 of copending Application No. 11/274,674. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope the germ-line transgenic avian which lays an egg contain an exogenous protein encoded by a transgene present in the germ-line of the transgenic avian, wherein the exogenous protein is produced in the transgenic oviduct as claimed in the instant application '671 encompasses a germline transgenic avian that lays an egg containing an exogenous protein encoded by a transgene.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21, 28-35, 37, 41, 46, 52-56, 59-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 11/100,255. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope the germ-line transgenic avian which lays an egg contain an exogenous protein encoded by a transgene present in the germ-line of the transgenic avian, wherein the exogenous protein is produced in the transgenic oviduct as claimed in the instant application '671 encompasses a transgenic avian comprising a transgene which includes a retroviral vector derived from an ALV wherein the vector contains a heterologous coding sequence operably linked to a promoter such that the transgenic avian expresses the heterologous coding sequence in an oviduct cell of the transgenic avian.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21, 28-35, 37, 41, 46, 52-56, 59-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 11/099,934. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope the germ-line transgenic avian which lays an egg contain an exogenous protein encoded by a transgene present in the germ-line of the transgenic avian, wherein the exogenous

protein is produced in the transgenic oviduct as claimed in the instant application '671 encompasses a transgenic avian comprising a transgene which includes a retroviral vector derived from a lentivirus wherein the vector contains a heterologous coding sequence operably linked to a promoter such that the transgenic avian expresses the heterologous coding sequence in an oviduct cell of the transgenic avian.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 59-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 11/337,361. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope the germ-line transgenic avian which lays an egg contain an exogenous protein encoded by a transgene present in the germ-line of the transgenic avian, wherein the exogenous protein is produced in the transgenic oviduct as claimed in the instant application '671 encompasses a method comprising recovering from an avian egg a protein wherein the protein is exogenous to the egg.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21, 28-35, 37, 41, 46, 52-56, 59-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 11/376,023. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope the germ-line transgenic avian which lays an egg contain an exogenous protein encoded by a transgene present in the germ-line of the transgenic avian, wherein the exogenous protein is produced in the transgenic oviduct as claimed in the instant application '671 is encompasses a method comprising obtaining an egg from a avian wherein the avian contains a transgene in its genome encoding an exogenous protein which is deposited in the egg; isolating the exogenous protein from the egg.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUMESH KAUSHAL
PRIMARY EXAMINER